DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 6, 2015

Fujifilm Medical Systems U.S.A., Inc.
Mary Moore
Senior Director, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K143732
Trade/Device Name: Fujifilm Endoscope Models EC-600HL and EC-600LS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: May 29, 2015
Received: May 29, 2015

Dear Mary Moore,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143732

Device Name
FUJIFILM Endoscope Models EC-600HL and EC-600LS

Indications for Use *(Describe)*
The FUJIFILM Endoscope Models EC-600HL and EC-600LS are intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s
FUJIFILM Endoscope Models EC-600HL and EC-600LS

Date: May 29, 2015

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

Mary K. Moore
Senior Director, Regulatory Affairs and Quality Assurance
Telephone: (973) 686-2498
Facsimile: (973) 686-2616
E-Mail: mkmoore@fujifilm.com

Identification of the Subject Device:

Proprietary/Trade Name:	FUJIFILM Endoscope Models EC-600HL and EC-600LS
Common Name:	Video Endoscope
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Colonoscope and Accessories (Flexible/Rigid), 21 CFR 876.1500
Product Code: FDF

Predicate Device

- FUJIFILM 600 Series Endoscope EC-600WL (K132210)

Intended Use / Indications for Use

The FUJIFILM Endoscope Models EC-600HL and EC-600LS are intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.

Technological Characteristics

The FUJIFILM Endoscope Models EC-600HL and EC-600LS are comprised of three main sections: an operation section, an insertion portion, and an umbilicus. The operation section controls the angulation (up/down/left/right) of the distal end of the endoscope. The insertion portion contains glass fiber bundles, several channels and a complementary metal-oxide-semiconductor (CMOS) image sensor. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CMOS image sensor to capture an image and display it on the monitor. The endoscope also contains several channels to deliver air/water and provide suction, as well as a forceps channel. The forceps channel is used to introduce endoscope accessories such as biopsy forceps during the procedure. The umbilicus section consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source.

The subject device is used in combination with FUJIFILM's video processor, light source and peripheral devices such as water tank, endoscope accessories, monitor, printer, electrosurgical instruments, foot switch, and cart. All of these were previously cleared in K132210.

A comparison of the technological characteristics between the subject and predicate devices is provided in the table below.

Device Description	EC-600WL (Predicate Device)	EC-600HL (Subject Device)	EC-600LS (Subject Device)
Indications for Use	This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.	This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.	This device is intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.
Insertion route	Retrograde	Retrograde	Retrograde
Viewing direction	Forward/ 0 degree	Forward/ 0 degree	Forward/ 0 degree
Observation range	2-100 nm	2-100 nm	2-100 nm
Field of view	140 degrees	170 degrees	170 degrees
Distal end diameter	12.0 millimeters	12.8 millimeters	11.5 millimeters
Flexible portion diameter	12.0 millimeters	12.8 millimeters	11.5 millimeters
Maximum diameter of insertion portion	13.2 millimeters	14.3 millimeters	13. 1 millimeters
Forceps channel diameter	3.8 millimeters	4.2 millimeters	Same as predicate
Working length	1690 millimeters	Same as predicate	Same as predicate
Total length	1990 millimeters	Same as predicate	Same as predicate

Processors and light sources	EPX-4440HD video processor systems (VP-4440HD Video Processor and XL-4450 Light Source, K102466) or EPX-4440HD with FICE systems (VP-4440HD Video Processor with FICE and XL-4450 Light Source, K140149),	EPX-4440HD video processor systems (VP-4440HD Video Processor and XL-4450 Light Source, K102466) or EPX-4440HD with FICE systems (VP-4440HD Video Processor with FICE and XL-4450 Light Source, K140149),	EPX-4440HD video processor systems (VP-4440HD Video Processor and XL-4450 Light Source, K102466) or EPX-4440HD with FICE systems (VP-4440HD Video Processor with FICE and XL-4450 Light Source, K140149),
Accessories	Channel Cleaning Brush WB4321FW2	Channel Cleaning Brush WB5021FW2	Channel Cleaning Brush WB5021FW2

Performance Data

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: ANSI/AAMI ES60601-1:2005; IEC 60601-1-2:2007; IEC 60601-1-6:2010; and IEC 60601-2-18:2009.

Biocompatibility of the subject devices was evaluated using the following consensus standards: ISO 10993-1:2009; ISO 10993-5:2009; and ISO 10993-10:2010.

Cleaning, disinfection, and sterilization were evaluated according to the following consensus standards: AAMI TIR30:2011; AAMI TIR12:2010; AAMI/ANSI/ISO 11135-1:2007; and AAMI/ANSI/ISO 17665-1:2006.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2013; ISO 8600-3:1997; and ISO 8600-4:1997.

Substantial Equivalence

The Endoscope Models EC-600HL and EC-600LS are as safe and effective as the FUJIFILM 600 Series Endoscope EC-600WL. Endoscope Models EC-600HL and EC-600LS have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate device. The minor technological differences between the Endoscope Models EC-600HL and EC-600LS and their predicate device were made for the purpose of overall product enhancement and general technological advancement, and raise no new issues of safety or effectiveness. Performance data demonstrate that the Endoscope Models EC-600HL and EC-600LS are as safe and effective as the Endoscope EC-600WL. Thus, the devices are substantially equivalent.

Conclusions

The Endoscope Models EC-600HL and EC-600LS are substantially equivalent to the cleared predicate based on intended use/indications for use and technological characteristics. The minor technological differences between the subject endoscopes and its predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject endoscopes have substantially equivalent performance to the predicate. Thus, the devices are as safe and effective as the predicate.